UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF
CHEMICAL SAFETY AND
POLLUTION PREVENTION

MEMORANDUM:

To: Julie Breeden-Alemi, DVM

From: Eric Bohnenblust, Ph.D. Entomologist

Secondary Review: Jennifer Saunders, Ph.D., Senior Entomologist

Date: June 13, 2016

Subject: PRODUCT PERFORMANCE DATA EVALUATION RECORD (DER)

THIS DER DOES NOT CONTAIN CONFIDENTIAL BUSINESS INFORMATION

Note: MRIDs found to be **unacceptable** to support label claims should be removed from the data matrix.

DP barcode: 340719
Decision no.: 379952
Submission no: 811040
Action code: 570
Product Name: Thermacell Mosquito Repellent
EPA Reg. No or File Symbol: 71910-2
Formulation Type: Spatial Repellent
Ingredients statement from the label with PC codes included:
d-Allethrin 21.97% PC: 004005
Application rate(s) of product and each active ingredient (lbs. or gallons/1000 square feet or per acre as appropriate; and g/m^2 or mg/cm^2 or mg/kg body weight as appropriate): One appliance per 225 square feet
Use Patterns: Outdoor spatial repellent to repel insects including mosquitoes and black flies. Do not use indoors or in tents.

I. Action Requested: To satisfy conditions of registration, the registrant submitted three studies for review to support efficacy claims against public health pests listed on the product label.

II. Background: To satisfy conditions of registration, the registrant submitted three MRIDs to support repellency claims for up to four hours for EPA Reg. No. 71910-2 against mosquitoes, black flies, biting flies, and other flying insects and bugs. The registrant has since submitted additional data and information to support repellency claims against mosquitoes (DPs 421168, 432851).The three studies submitted to satisfy the conditions of registration are reviewed below.

III. MRID Summary: (ethics and primary reviews are attached)

47142402. ThermaCell® Area Repellent Field Test Report.

(1) non-GLP

(2) **Ethics Summary:** Per the attached ethics review dated May 5, 2016, this study does not meet the Agency's

ethical standards to support a pesticide product.

(3) **Methods:** This study tested efficacy of a spatial repellent containing 21.97% d-allethrin outdoors on human subjects against adult *Aedes* spp. mosquitoes. The product was tested at a rate of one appliance per 15-ft diameter area (176 ft^2). The appliance was turned on 30 minutes prior to testing. Six human subjects exposed bare skin on one calf. Subjects were placed upwind, downwind, or perpendicular to the wind at a distance of 3.75, 7.5, and 15 ft from the appliance depending. Efficacy at each distance was tested for a 30 minute period. The same subjects were used in the control treatment after cleaning their exposed skin and changing into clean clothes. The test was repeated over the course of four evenings.

(4) **Results:** At a distance of 15 feet, the average percent repellency ranged from 33.6% to 78.9% with an overall total of 62.0%. At a distance of 7.5 feet, the average percent repellency ranged from 72.7% to 88.5% with an overall total of 81.1%. At a distance of 3.75 feet, the average percent repellency ranged from 66.2% to 85.7% with an overall total of 79.8%. The average percent repellency for all three distances combined was 73.9%.

(5) **Conclusion: Unacceptable.** This study is not acceptable to support product efficacy for EPA Reg. No. 71910-2 because it does not meet the Agency's ethical standards per the attached ethics review dated May 5, 2016. From the science perspective, this study was conducted on a smaller area (176 ft^2) than listed on the product label (225 ft^2). Also, the study does not state how long the product was tested; current label claims for the mats specify four hours of protection time. Additionally, the study only tested one genera of mosquitoes.

47142403. ThermaCell® Area Repellent Field Test Report.

(1) **Background:** The registrant confirmed through email on May 10, 2016 that they did not want to use MRID 47142403 to support EPA Reg. No. 71910-2. This MRID was reviewed by the contractor prior to being withdrawn for consideration to support product efficacy and that review is attached (please note that the attached contractor review is not a final review for this MRID). An ethics review was not performed prior to this study being withdrawn for consideration to support product efficacy. This study tested efficacy of the product against sand flies.

(4) **Conclusion: Extraneous.** This MRID does not support efficacy claims this product because it was withdrawn from consideration for supporting product efficacy.

47142404. ThermaCell® Area Repellent Field Test Report.

(1) GLP

(2) **Ethics Summary:** Per the attached ethics review data May 5, 2016, this study meet the Agency's ethical standards to support a pesticide product.

(3) **Methods:** This study tested efficacy of a spatial repellent containing 21.97% d-allethrin outdoors on human subjects against black flies (*Simulium venustum* and *Prosimilium hirtipes*). The product was tested at a rate of one appliance per 15-ft diameter area (176 ft^2) over the course of a four hour period. The appliance was turned on 30 minutes prior to testing. Six human subjects exposed bare skin on one calf. Subjects were placed upwind, downwind, or perpendicular to the wind at a distance of 3.75, 7.5, and 15 ft from the appliance depending. Efficacy at each distance was tested for a 30 minute period. The same subjects were used in the control treatment after cleaning their exposed skin and changing into clean clothes. The test was repeated over the course of four evenings. Data were analyzed using numerous t-tests.

(4) **Results:** The percent repellency when subjects in all directions (parallel, upwind, and downwind) from the unit were combined was 73.13% at when subjects were 3.75 ft from the appliance, 61.1% when subjects were 7.5 ft from the appliance, and 46.1% when subjects were 15 ft from the appliance. When all three distances and all directions from the unit were considered together, percent repellency was 44.9% (Note: 44.9% is listed in the text for repellency for all directions at only 15 ft from the unit which is inconsistent with the results presented in the tables). When species were considered individually, the percent repellency of *P. hirtipes* at all three distances combined was 75%, while repellency against *S. venustrum* was 54.6%. The number of *S. venustrum* collected was about four times

greater than the number of *P. hirtipes*. All of the above numerical percentages above were statistically significant; however, when the subjects were analyzed separately by direction in relation to the appliance many percent repellency values were statistically non-significantly different from the control suggesting that in many cases repellency is adequate. Indeed, the percent repellency of black flies on subjects downwind and 7.5 and 15 ft from the appliance was less than 70% and non-significantly different from the control.

(5) **Conclusion: Unacceptable.** This study does not support repellency claims against black flies because repellency did not reach 75% and in many cases was not significantly different from the control. While repellency of *P. hirtipes* did reach 75% the number individuals of this species was about 20% of the overall number of black flies. Because the study did not parse the number individuals for each species, we cannot adequately evaluate whether the repellency provided against *P. hirtipes* is meaningful. Further, the statistical analyses as provided are inappropriate for the study; a more complex model should have been used which could account for effects based on direction and distance from the appliance.

IV. EXECUTIVE DATA SUMMARY:

(A) The data submitted above do not support product efficacy or any claims against mosquitoes, sand flies, or black flies or any other pests.

V. LABEL RECOMMENDATIONS:

(1) No changes are needed to the Directions for Use.

(2) The following marketing claims are acceptable: Please see comments on the attached marked version of the latest accepted label.

(3) The following marketing claims are unacceptable: Please see comments on the attached marked version of the latest accepted label.

(4) The following MRIDs should be removed from the data matrix, as they are classified as "unacceptable" to support the product: 47142402, 47142403, 47142404

(5) Note to reviewer/PM: The efficacy claims against mosquitoes for this product are supported by an MRID reviewed under DP 421168.